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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|--------------------------|---------------------|------------------|
| 10/671,064 | 09/25/2003 | Lars Hojlund Christensen | 6535.200-US | 5846 |
| 23650 | 7590 | 05/26/2006 | EXAMINER | |
| NOVO NORDISK, INC. PATENT DEPARTMENT 100 COLLEGE ROAD WEST PRINCETON, NJ 08540 | | | FORTUNA, ANA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1723 | |

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/671,064 | Applicant(s) CHRISTENSEN ET AL. | |
| | Examiner Ana M. Fortuna | Art Unit 1723 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22, 24 is/are rejected.
- 7) ☒ Claim(s) 23 and 25-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17-20, 21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laustsen et al (US Patent 6,582,606)(hereinafter patent '606) in view of Weiss et al (US Patent 5,453,200)(hereinafter patent 200).

Patent '606 discloses microfiltration of **fermentation derived products** at temperature of 65 degree C, by microfiltration, or combination of microfiltration and ultrafiltration membranes (abstract, column 2. lines 6-30, and column 5, lines 4-8). The fermentation derived products are disclosed as containing protein, e.g. hydrolases, protease, cellulase, lipase, etc (see column 2, lines 37-68, and column 3. lines 168, and column 4, lines 1-47).

Performing the filtration a temperature of **66** degree C. (one degree higher than reference '606) as recited in claim 1 is not disclosed in patent '606 (Laustsen et al).

Patent '200 (Weiss et al) teaches the purification of fermentation broth containing proteins including purification by membrane filtration (microfiltration, ultrafiltration) or protein evaporation at **80 degree C.** (see claims 1-11, abstract, column 2, lines 42-6f8, column 3, lines 65-68, column 4, lines 1-27, and column 6, lines 15-17). The

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concentrated protein from the broths in patent '200, is disclosed as the family of hydrolases, e.g proteases, amylases, lipases (see claim 3); which correspond to the same family in the broth composition of patent '606.

Weiss ('200) teaches that the later group of protein is capable of standing 80 degree C without denaturation (based on the evaporation temperature of 80 degree C).

I would have been obvious to one skilled in the art at the time the invention was made to perform the microfiltration at a temperature higher than the 65 degree C disclosed in '606, e.g. a temperature not affecting protein denaturation, or temperatures lower than 80 degree C suggested in patent '200 for protein concentration. The increase of 1 degree in temperature in the process of patent '006 does not appear to be significant to change the process conditions, or affecting the microfiltration concentration in '606. One skilled in the art at the time the invention was made can expect an increase of one degree caused by ambient temperature conditions, friction of the fluid with the membrane surface.

The temperature can be further increased at values higher than 66, e.g. lower than 80 degree C. based on membrane material resistant to temperature.

Patent '200 does not teach a particular temperature for the microfiltration or ultrafiltration, which suggests that ambient temperatures are suitable.

As to claim 2, using activated carbon is alternative depending on whether color or other impurities are desire to be removed from the broth **prior** or together with filtration. The later claim only excludes the activated carbon "during microfiltration"; the term "prior" does not suggest that the membrane is contacted with the activated carbon.

Furthermore, reference '200 teaches purification of fermentation by microfiltration/ultrafiltration and without activated carbon, e.g. other adsorbents are alternatively suggested, e.g. bentonite, calcium, aluminum, phosphate; which are not exclude fro claim 2 (see claim 5, column 4, lines 4-26).

Regarding claims 8-12, the membrane materials and batch and continuous process are disclosed in '606 (column 5, lines 4-12, and column 6, second paragraph).

Limitations of claims 13-15, e.g. a membrane with molecular weight lower than the molecular weight of the fermentation product is all what is needed for its retention, one skilled in the art at the time the invention was made can expect its retention by membranes with molecular weight cut-off lower than the required, which further retain additional components with the selected molecular weight. The term microfiltration includes pores between 0.02-10 microns, therefore, molecular weight cut-off within this pore size range, are expected to concentrate the proteins from the fermentation broth, as suggested in the references above. .

As to claims 17-20, the retained product should be at the fed temperature during the process, e.g. 65 degree C, for the filtration period, for the selected operating time in either batch or continuous process of patent '606.

As to claims 21-22, 24, the proteins are discussed above.

3. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laustsen et al (US Patent 6,582,606)(hereinafter patent '606) in view of Weiss et al (US Patent 5,453,200)(hereinafter patent 200) as applied to claim 5 above, and further in view of Rochilgo (US Patent 5,143,630). Patent '606 and '200 fails to disclose vibrating the

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membrane 9 or cleaning the membrane by vibrating). Rochilgo teaches membranes suitable for separation of components from a fermentation process, the filter operation includes vibration, e.g. by rotation (abstract, column 12, lines 53-68). It would have been obvious to one skilled in the art at the time the invention was made to perform the microfiltration as disclosed in the discussed patents above, in combination with vibration as suggested in Rochilgo, or conventional vibration means, e.g. ultrasonic vibration application, for maintaining the membrane surface clean during the process.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Laustsen et al (US Patent 6,582,606)(hereinafter patent '606) in view of Weiss et al (US Patent 5,453,200)(hereinafter patent 200), as applied to claim 1 above, and further in view of Hussain (6,814,862).

Patent '606 and '200 fail to disclose the cleaning process or back pulse (back-suck). Cleaning membrane deposited solids by periodic reversal of permeate is known in the art as evidenced by Hussain (column 4, lines 13-24). It would have been obvious to one skilled in the art at the time the invention was made to clean the membrane, either Microfiltration or ultrafiltration by reversing the flow under pressure, e.g. back wash, or backpulse, as suggested in Hussain.

Allowable Subject Matter

5. Claims 23, 25-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: treatment of the particular proteins under the claimed temperature conditions is not disclosed or suggested in the prior art of record.

Response to Arguments

7. Applicant's arguments filed 3/14/06 have been fully considered but they are not persuasive. The rejection based on patent 5,508,196 is withdrawn in view of applicant's amendment. Rejection of claims over Laustsen et al (6,582,606) in view of Weiss et al (5,453,200) discussed in the record is maintained. The rejection is considered proper for reasons discussed in the paragraphs above. Claim 1 does not exclude the activated carbon treatment; and claim 2 does not exclude the activated carbon treatment "prior to" the microfiltration or membrane filtration. Claim 1 differs from the prior art in one degree in temperature during the microfiltration step, which has not been found sufficient improvement or reasons for patentability, because reference '200 separates the same type of protein by microfiltration at room temperature, e.g. no specific temperature is disclosed as critical. The later reference also teaches concentration of the protein at 80 degree C, which suggests that there is not variation in protein quality when exposed to at 80 degree temperature. The membrane materials used in '606 are high temperature resistance, therefore, increasing the temperature for a few degrees higher, e.g. higher than 65 degree C, does not appear to cause a negative effect on the membrane, e.g. PS, PTFE (see '606, column 5, first paragraph).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

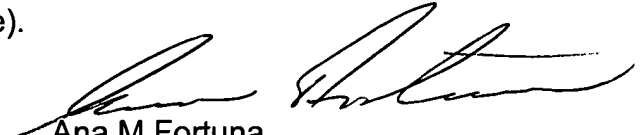
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ana M Fortuna
Primary Examiner
Art Unit 1723

AF
May 23, 2006